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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/636,129	08/07/2003	Philip Fuchs	P27-052	2814

7590 01/24/2006
Henry D. Coleman
714 Colorado Avenue
Bridgeport, CT 06605

EXAMINER

ANDERSON, REBECCA L

ART UNIT PAPER NUMBER

1626

DATE MAILED: 01/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/636,129	FUCHS ET AL.	
	Examiner	Art Unit	
	Rebecca L. Anderson	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 October 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) 11,13-21 and 24-31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10,12,22 and 23 is/are rejected.
- 7) ☒ Claim(s) 1-10,12,22 and 23 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

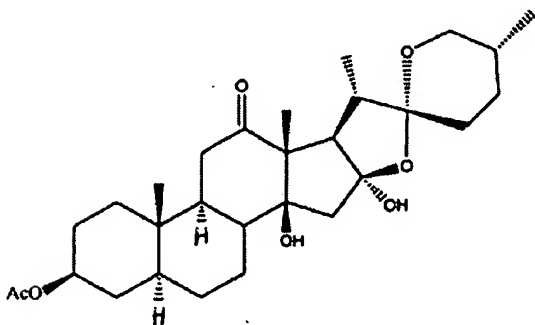
- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. <u>012006</u> . |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____. | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

Claims 1-31 are currently pending in the instant application. Claims 11, 13-21 and 24-31 are withdrawn from consideration as being for non-elected subject matter and claims 1-10, 12, 22 and 23 are objected and rejected.

Election/Restrictions

Applicants' election of Group II, and the further election of the compound



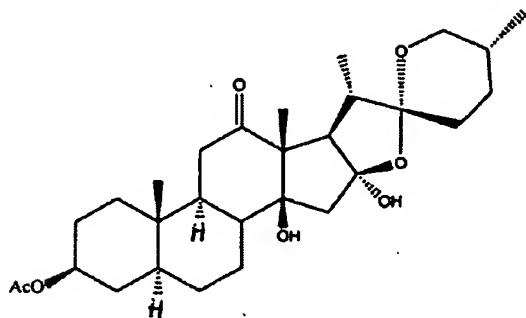
with traverse in the response filed 27

October 2005 is acknowledged.

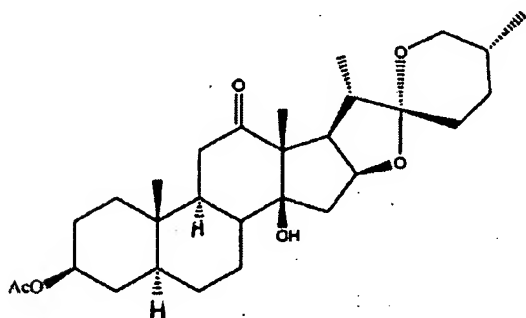
Applicants' traversal is on the grounds that there is no undue burden for the examiner. This traversal is not persuasive as each group is directed to art recognized divergent subject matter, which require different searching strategies for each group. Moreover, the examiner must perform a commercial database search on the subject matter of each group in addition to a paper search, which is quite burdensome to the examiner. Accordingly, restriction as has been presented in this application is proper.

Therefore, as stated on pages 3 and 4 of the restriction requirement, the elected invention for search and examination is:

The method of preparing the compound of the formula



by oxidizing a hydrocarbon of the formula:



comprising reacting the hydrocarbon in an anhydrous solvent with a chromium [VI]oxidant and a co-oxidant at a reaction temperature of between about -50 degrees Celsius to about 0 degrees Celsius, thereby catalytically and chemo specifically oxidizing the hydrocarbon: (I) substantially stereo specifically at a tertiary carbon to form a hemiacetal.

The remaining subject matter of claims 1-10, 12, 22 and 23 not drawn to the above elected invention and the subject matter of claims 11, 13-21 and 24-31 stands withdrawn under 37 CFR 1.142(b) as being for non-elected subject matter. The remaining methods of preparation of hydrocarbons which are not within the elected invention, which are independent and distinct from the elected invention and do not have unity with the elected compound and are therefore withdrawn by means of a

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restriction requirement within the claims are, for example, the methods of preparing hydrocarbons as found in claims 14, 16, 18, 20, etc.

The above mentioned withdrawn methods of preparing hydrocarbons which are withdrawn from consideration as being for non elected subject matter differ materially in structure and composition of the final products of the elected invention. The withdrawn processes prepare compounds which differ from those of the elected invention, such as, for example, by a thiazolidine, quinoline, thiophene, morpholine, oxazole, pyrimiding, pyrazine, pyran, furan, etc., which are chemically recognized to differ in structure, function, and reactivity. This recognized chemical diversity of the compounds can be seen by the various classification of these compounds in the U.S. classification system, i.e. class 549 subclass (200)+ furanyl, class 549 subclass (1)+ thiophene, class 548 subclass (215)+ oxazole and class 548 subclass (146)+ thiazole, etc. Therefore, again, the processes which are withdrawn from consideration as being for non-elected subject matter differ materially in structure and composition of the final product and have been restricted properly as a reference which anticipated but the elected subject matter would not even render obvious the non-elected subject matter. These withdrawn processes are independent and distinct from the elected invention and do not have unity with the species elected and are therefore withdrawn by means of a restriction requirement within the claims.

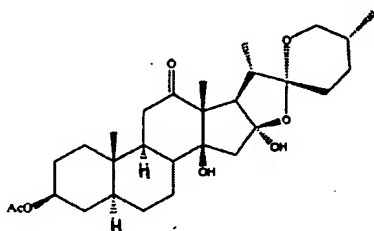
The requirement is still deemed proper.

Claim Objections

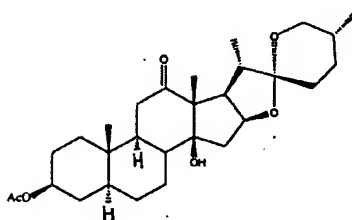
Claims 1-10, 12, 22 and 23 are objected to as containing non-elected subject

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matter. Claims 1-10, 12, 22 and 23 presented drawn solely to the elected invention for search and examination as identified supra as the method of preparing the hydrocarbon



of the formula



by oxidizing a hydrocarbon of the formula:

comprising reacting the hydrocarbon in an anhydrous solvent with a chromium [VI]oxidant and a co-oxidant at a reaction temperature of between about -50 degrees Celsius to about 0 degrees Celsius, thereby catalytically and chemo specifically oxidizing the hydrocarbon: (I) substantially stereo specifically at a tertiary carbon to form a hemiacetal, would overcome the instant objection.

Claims 7-10 and 12 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim must refer in the alternative. See MPEP § 608.01(n). Claim 7 is dependent on both claim 5 and 6, not in the alternative. Claim 9 is dependent on both claims 1 and 2, not in the alternative. It is suggested that claims 7 and 9 be amended to be dependent on only one claim, for example, as dependent on, "the method of one of claims 5 or 6."

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-10, 12, 22 and 23 are rejected under 35 U.S.C. 112, first paragraph, because the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

As stated in the MPEP 2164.01 (a), "There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue."

In *In re Wands*, 8 USPQ2d 1400 (1988), factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described. They are:

1. the nature of the invention,
2. the state of the prior art,
3. the predictability or lack thereof in the art,
4. the amount of direction or guidance present,
5. the presence or absence of working examples,
6. the breadth of the claims,

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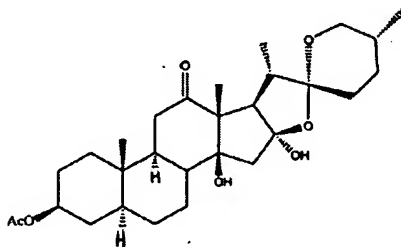
7. the quantity of experimentation needed, and

8. the level of the skill in the art.

In the instant case

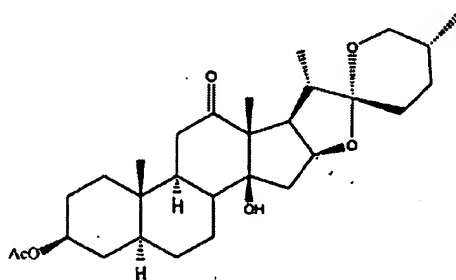
The nature of the invention

In the instant case, Applicants' elected invention is the method of preparing the



hydrocarbon of the formula

by oxidizing a



hydrocarbon of the formula:

comprising

reacting the hydrocarbon in an anhydrous solvent with a chromium [VI]oxidant and a co-oxidant at a reaction temperature of between about -50 degrees Celsius to about 0 degrees Celsius, thereby catalytically and chemo specifically oxidizing the hydrocarbon:
 (I) substantially stereo specifically at a tertiary carbon to form a hemiacetal.

The state of the prior art and the predictability or lack thereof in the art

The state of the art according to Lee et al. is that in regards to research involving hyperactive analogues of the cephalostatin/reiterating family of marine natural products, it has proven difficult to oxidatively prepare intermediates for synthesis as dioxiranes

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have been shown to smoothly oxidize tertiary C-H bonds of saturated spiroketals, reaction of the olefin with DMDO or TFDO produces complex mixtures, and neither of the epoxy isomers undergoes additional C-H oxidation under extended reaction times with the dioxirane reagents.

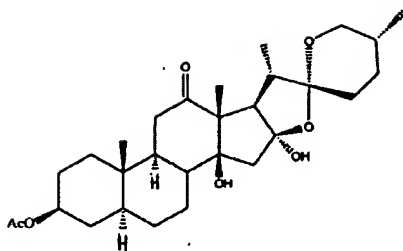
The amount of direction or guidance present and the presence or absence of working examples

There is no direction or guidance present in the instant specification for how to use the instantly claimed process to arrive at any useful final product, such as cephalostatins and ritterazines, which are a family of forty-five structurally unprecedented marine products with extreme cytotoxicity against human tumors. While the instant specification states that the claimed methods have wide application in the oxidation of a variety of substrates for application in combinatorial chemistry, the specification fails to disclose how to use the intermediate products prepared by the instantly claimed method for the preparation of any useful final product, such as cephalostatins and ritterazines. There are no working examples present in the instant application showing how to use the intermediate compounds prepared by the claimed process to produce any useful final product, such as cephalostatins and ritterazines. Therefore, the instant invention is not enabled.

The breadth of the claims

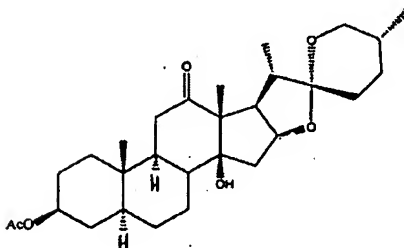
The instant breadth of the rejected claims is the method of preparing the

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hydrocarbon of the formula

by oxidizing a



hydrocarbon of the formula:

comprising reacting the

hydrocarbon in an anhydrous solvent with a chromium [VI]oxidant and a co-oxidant at a reaction temperature of between about -50 degrees Celsius to about 0 degrees Celsius, thereby catalytically and chemo specifically oxidizing the hydrocarbon: (I) substantially stereo specifically at a tertiary carbon to form a hemiacetal.

The quantity of experimentation needed and the level of the skill in the art

While the level of the skill in the combinatorial chemical arts is high, it would require undue experimentation of one of ordinary skill in the art to prepare any useful final product, such as cephalostatins and ritterazines, as the state of the art discloses the difficulty in the preparation of intermediates for synthesis and as the specification fails to provide any disclosure as to how to use the intermediate compounds prepared by the instantly claimed invention to prepare any useful final product in combinatorial chemistry. There is no guidance or working examples present for preparing useful final products from the intermediate compounds prepared by applicants' instantly claimed

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invention. Therefore, based on the evidence regarding each of the above factors, the specification, at the time the application was filed, would not have taught one skilled in the art how to use the full scope of the claimed invention without undue experimentation.

Non-elected Subject Matter Claim Rejections - 35 USC § 102

The following 35 USC 102(b) rejections apply to non-elected subject matter.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The non-elected subject matter of claims 1, 2, 9 and 12 is rejected under 35 U.S.C. 102(b) as being anticipated by Yamazaki et al.

Yamazaki et al. discloses the process of oxidizing arenes to the corresponding quinones (i.e. one or more secondary carbons form a ketone or dione). The process is disclosed in the reaction at the bottom of page 3355 and on page 3357 wherein H₅IO₆ (periodic acid, a co-oxidant) is dissolved in acetonitrile (an anhydrous solvent) with vigorous stirring, and then CrO₃ (a chromium [VI] oxidant) was dissolved to the solution. The resulted solution was cooled to 5 degrees Celsius (about 0 degrees Celsius). 2-methylnaphthalene (a hydrocarbon, substituted, non-hetero, aromatic, bicyclic compound containing one or more alkyl and aryl groups) dissolved in acetonitrile (an anhydrous solvent) was added all at once to the above solution with stirring.

Conclusion

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rebecca L. Anderson whose telephone number is (571)

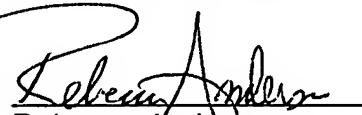
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272-0696. Mrs. Anderson can normally be reached Monday through Friday 5:30AM to 2:00PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Mr. Joseph K. McKane, can be reached at (571) 272-0699.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Rebecca Anderson
Patent Examiner
Art Unit 1626, Group 1620
Technology Center 1600

January 20, 2006